

## **REMARKS**

### ***Status of the Claims***

Claims 22-48 and 51-53 are pending. Claims 22, 30, 42, 51, and 52 are amended. Claims 49 and 50 are canceled without prejudice or disclaimer to the subject matter therein.

Support for the amendments are found throughout the specification and in the claims as originally filed. Applicants respectfully submit the above amendments do not constitute new matter and request entry of the amendments.

### ***Allowable Subject Matter***

Applicants greatly appreciate the Examiner's indication that claims 29, 31, 51, and 53 would be allowable if re-written in independent form.

### ***Specification***

The specification is objected to because the sequences on page 61 do not have SEQ ID NOs.

Applicants have amended the specification to insert SEQ ID NOs for these sequences. This response is filed via EFS-Web. The Legal Framework for EFS-Web states:

The requirements of 37 CFR 1.52(e)(3)(ii), (4), and (6) are not applicable to computer program listings, sequence listings, and tables submitted as text files via EFS-Web.... [T]he specification must contain an incorporation-by-reference of the material in the text file in a separate paragraph identifying the name of the text file, the date of creation, and the size of the text file in bytes as per 37 CFR 1.52(e)(5).

If a sequence listing text file submitted via EFS-Web complies with the requirements of 37 CFR 1.824, the filer need not submit (i) any additional copies of the sequence listing pursuant to 37 CFR 1.821(e) nor (ii) the statement described in 37 CFR 1.821(f)....

If a filer submits a sequence listing (under 37 CFR 1.821(c)) as a text file via EFS-Web in response to a requirement under 37 CFR 1.821(g) or (h), the sequence listing text file must be accompanied by a statement that the submission does not include any new matter which goes beyond the disclosure of the application as filed. However, if the sequence listing text file complies with the requirements of 37 CFR 1.824, the filer need not submit (i) any additional copies of the sequence listing pursuant to 37 CFR 1.821(e) nor (ii) the statement described in 37 CFR 1.821(f).<sup>1</sup>

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<sup>1</sup> See <http://www.uspto.gov/ebc/portal/efs/legalframework.pdf>, page 6.

Accordingly, Applicants do not provide a paper copy of the sequence listing pursuant to 37 CFR 1.821(e) or the statement described in 37 CFR 1.821(f). As required by 37 CFR 1.821(g), Applicants hereby state that this submission does not include any new matter.

In view of the foregoing, this objection is moot.

***Claim Rejections – 35 U.S.C. § 112, 1<sup>st</sup> Paragraph (Enablement)***

Claims 22-28, 30, 32-50, and 52 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, because the specification, while being enabling for the suppression of SSIII, BEI, and BEII with antisense sequences comprising at least 95% of SEQ ID NOS: 1, 4, and 6, respectively, allegedly does not reasonably provide enablement for cosuppression molecules or duplex RNA molecules that suppress SSIII, BEI, and BEII.<sup>2</sup>

Applicants respectfully traverse.

The Office Action contends that the specification does not provide any guidance for cosuppression and duplex RNA gene suppression.<sup>3</sup>

Applicants respectfully disagree.

The claims relate to plant cells and plants comprising foreign nucleic acid molecules that, via antisense, cosuppression, RNAi, or a combination thereof, reduce expression of SSIII, BEI, and BEII genes. Antisense, cosuppression, and RNAi are examples of post transcriptional gene silencing (PTGS) techniques.<sup>4</sup> The basic requirement for PTGS is that the silencing construct is homologous to the gene sequence to be downregulated.<sup>5</sup> Indeed, it is well known by the those of skill in the art that antisense, cosuppression, and RNAi

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<sup>2</sup> See Office Action, page 2.

<sup>3</sup> *Id.* at page 3.

<sup>4</sup> See, e.g., Vauchert et al. (Trends in Genetics 17:29-35, 2001), page 29 (discussing cosuppression and RNAi as acting on the post transcription level); Singh et al. (Biochemical Society Transactions Vol. 28 part 6, pages 925-927, 2000; **Exhibit A**), page 925 (“PTGS has been induced in plants either through the use of antisense or cosuppression constructs”) and page 926 (Figure 1); Wesley et al. (The Plant Journal 27(6): 581-590, 2001, **Exhibit B**), abstract and page 582, right column, end of second paragraph.

<sup>5</sup> See, e.g., Vauchert, page 29 (teaching that cosuppression at the post transcriptional level occurs when the homology is within the coding region); Singh et al., page 926, right column, “Results and Discussion.”

techniques will lead to downregulation, albeit at different frequencies at which desired silenced plants are obtained.<sup>6</sup> Accordingly, once a sequence of interest is identified, one of skill in the art can develop a homologous gene silencing construct to inhibit the expression of the sequence.

The specification discloses coding sequences for the SSIII, BEI, and BEII genes.<sup>7</sup> The specification teaches methods of making transgenic plants comprising sequences that reduce the expression of SSIII, BEI, and BEII, as well as methods of testing SSIII, BEI, and BEII activity.<sup>8</sup> The specification also teaches methods of preparing gene silencing constructs and that methods of reducing expression via antisense, co-suppression, and RNAi are well known in the art.<sup>9</sup> The specification further cites to a document disclosing an SSIII cosuppression construct.<sup>10</sup> Accordingly, the specification teaches various coding sequences of interest, methods of preparing gene silencing constructs homologous to these sequences, and specifically exemplifies a transgenic plant comprising sequences that reduce the expression of SSIII, BEI, and BEII.

The Office Action cites Vauchert et al. to support its assertion that cosuppression is unpredictable.<sup>11</sup>

Applicants respectfully disagree.

Vauchert discriminates between two types of gene silencing: (1) transcriptional gene silencing (TGS); and (2) post transcriptional gene silencing (PTGS). Cosuppression occurs at either the transcriptional level (i.e., TGS) or the post transcriptional level (i.e., PTGS).<sup>12</sup>

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<sup>6</sup> See, e.g., Singh et al. at page 926 (Figure 1); Wesley et al. at page 587 (Table 1).

<sup>7</sup> See, e.g., Specification, page 47; Sequence Listing.

<sup>8</sup> See, e.g., Specification, at page 58, line 27 to page 62, line 5.

<sup>9</sup> *Id.* at pages 22-27.

<sup>10</sup> See, e.g., Specification, page 4 (citing WO/2000/008184). A corresponding English language document (U.S. Patent No. 6,596,928) was previously cited in an Information Disclosure Statement; see also MPEP § 2164.05 ("The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.")

<sup>11</sup> See Office Action, page 3.

<sup>12</sup> See Vauchert, page 29, left column.

Cosuppression at the transcriptional level occurs when the homology is within the promoter, whereas cosuppression at the post transcriptional level occurs when the homology is within the coding region.<sup>13</sup> According to Vaucheret, RNAi also acts at the post transcriptional level.<sup>14</sup>

The claims relate to coding sequences. As such, the silencing effect takes place at the post transcriptional level (PTGS). Vauchert's review does not teach that cosuppression at the post transcriptional level is unpredictable. Rather, Vauchert "focuses on TGS."<sup>15</sup> Indeed, the Office Action's citation to Vauchert is specifically directed to TGS.<sup>16</sup> Accordingly, because the claims relate to antisense, cosuppression, and RNAi—post transcriptional gene silencing methodologies<sup>17</sup>—the Office Action's reliance on Vauchert is misplaced.

In view of the foregoing, Applicants respectfully submit that one of skill in the art can make and use the full scope of the claims, in view of Applicant's disclosure and the knowledge of one of skill in the art, without undue experimentation. Accordingly, Applicants respectfully request withdrawal of this rejection.

***Claim Rejections – 35 U.S.C. § 112, 1<sup>st</sup> Paragraph (Written Description)***

Claims 22-28, 30, 32-50, and 52 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph as allegedly failing to comply with the written description requirement. Specifically, the Office Action asserts that the specification does not disclose a working example of cosuppression.

Applicants respectfully traverse.

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<sup>13</sup> See *id.* at page 29 (glossary).

<sup>14</sup> See *id.*

<sup>15</sup> See *id.* at page 29, right column; see also sub-headings throughout Vauchert.

<sup>16</sup> See *id.* at page 29, right column, last sentence.

<sup>17</sup> See, e.g., Vauchert, page 29; Singh et al., page 925 and page 926 (Figure 1); Wesley et al., abstract and page 582, right column, end of second paragraph.

As an initial matter, the specification discloses a reference that contains an SSIII cosuppression construct.<sup>18</sup> As such, Applicants are not required to provide a working example for such a construct.<sup>19</sup>

Applicants further submit that, as discussed above, the specification teaches various coding sequences of interest, methods of preparing gene silencing constructs homologous to these sequences, and specifically exemplifies a transgenic plant comprising sequences that reduce the expression of SSIII, BEI, and BEII. One of skill in the art would understand that, in view of Applicant's disclosure and the knowledge of one of skill in the art, Applicants were in possession of the full scope of the claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

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<sup>18</sup> See, e.g., Specification, page 4 (citing WO/2000/008184).

<sup>19</sup> See, e.g., MPEP § 2163 (II) (discussing that what is known to one of ordinary skill in the art need not be disclosed in detail in the specification).

**CONCLUSION**

It is believed that these amendments and remarks should place this application in condition for allowance. A notice to that effect is respectfully solicited.

If the Examiner has any questions relating to this response or the application in general, then he is respectfully requested to contact the undersigned so that prosecution of this application may be expedited.

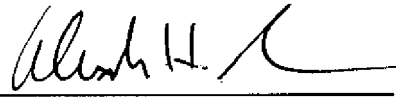
This response is being filed within the three month shortened statutory period. Accordingly, no fees are due. Should the USPTO determine any fees are due, however, the USPTO is authorized to charge such fees to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

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Dated: July 29, 2009

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